K120863

APR 19 2012

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510(k) Summary

Wholey™ Guide Wire System

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.
Applicant	Covidien llc, formerly ev3, Inc.
Submitter	Covidien llc 3300 Campus Drive, Suite N550 Plymouth, MN 55441 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	David Robertson Regulatory Affairs Specialist
Date Prepared	February 3, 2012
Device Trade Name	Wholey™ Guide Wire System
Device Common Name	Catheter Guide Wire
Classification Name	Wire, Guide, Catheter (21 CFR 870.1330), Product Code DQX
Classification Panel	Cardiovascular
Predicate Devices	Advanced Cardiovascular Systems Inc., Wholey™ Hi-Torque® Guide Wire (K861765)
Device Description	The Wholey™ Guide Wire System is a 0.035" guide wire available in lengths of 145, 175, 260 and 300cm. The distal tip flex configurations are Standard, Floppy, and Intermediate. Tip shape is Straight or Modified J. The guidewire is composed of a stainless steel core, green PTFE (polytetrafluoroethylene) coated coil, white PTFE sleeve, platinum-tungsten marker coil, and optional extension system connector. The proximal end of the core is covered by a white PTFE sleeve that terminates at 100cm from the distal tip. The distal 100cm of the guidewire is covered with a green PTFE pre-coated coil. The PTFE coated coil and

platinum-tungsten coil are welded to the core on the very distal tip. The distal tip is shapeable and radiopaque.

A torque device is packaged with the guide wire as an accessory. The polycarbonate/brass torque device is designed to be secured to the proximal portion of a guide wire with a diameter, from 0.020" – 0.040" (0.50mm to 1.01mm) to facilitate steering of the guide wire within the vascular anatomy.

A Wholey Extension Wire is an available accessory consisting of a PTFE coated stainless steel guide wire attachment which is 0.035" (0.900 mm) in diameter and 155 cm in length. It is exclusively compatible with 0.035" (0.900 mm) Wholey guide wires which have been modified for the attachment of the Wholey Guide Wire Extension to facilitate device exchange. Refer to the Wholey Guide Wire Extension instructions for use.

Indication for Use

The Wholey Guide Wire System is intended to facilitate the placement and exchange of interventional devices during diagnostic or therapeutic interventional procedures. The guide wire can be torqued to facilitate navigation through tortuous arteries and/or avoid unwanted side-branches.

Performance data

Bench testing and a GLP animal study were performed to support a determination of substantial equivalence. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. Test methods were developed using *FDA Coronary and Cerebrovascular Guidewire guidance and ISO 11070:1998* in order to demonstrate equivalence of the Wholey Guide Wire System to the predicate device. A list of applicable non-clinical tests included performed at baseline and one year aging include:

- Distal Pull Strength
- Combined Load
- Torque Response
- Tip Flexibility
- Coating Durability
- Lubricity and Catheter Compatibility
- Pouch Peel
- Dye Penetration
- Linear Stiffness
- Dimensional
- Visual
- Fracture - ISO
- Flex – ISO
- Corrosion
- Strength of Union – Distal
- Tip Shape Retention
- Tip Load
- Hypotube Flex
- Jacket Adhesion
- Body Stiffness (3-Point Bend)
- Particulate

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- Radiopacity
- Thermal Conditioning and Packaging Distribution
- Lateral Stiffness

Biocompatibility testing per ISO 10993 series was performed on the Wholey Guide Wire System and test results met the specified acceptance criteria.

- Cytotoxicity
- Kligman Maximization Test
- Systemic Toxicity
- Rabbit Pyrogen
- Hemolysis
- Complement Activation Assay
- Thrombogenicity
- Lee and White Coagulation
- Unactivated Thromboplastin Time Assay
- USP Physicochemical Test
- Inhibition and Enhancement

A GLP animal study was completed to evaluate safety and performance of the Wholey Guide Wire System compared to the currently marketed predicate device. The study showed the Wholey Guide Wire System is substantially equivalent to the predicate device for the evaluated safety and performance criteria.

Summary of Substantial Equivalence

The Wholey Guide Wire System has the following similarities to the predicate devices:

- Similar basic design and fundamental scientific technology
- Similar operating principle
- Similar core wire materials
- Similar wire diameter
- Similar wire lengths
- Similar tip styles

The characteristics that differ from the predicate device are the:

- Distal core head
- Radiopaque marker coil
- PTFE coated distal 8cm
- Lack of intermediate joint at 8cm
- Lack of adhesive between coil and sleeve

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	• White PTFE sleeve • Braze extension adapter
Conclusion	Based on the similar indications for use, technological characteristics, and results from in-vitro and in-vivo testing, Covidien llc considers the Wholey™ Guide Wire System substantially equivalent to the Wholey™ Hi-Torque® Guide Wire (K861765).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 19 2012

Covidien LLC
c/o Mark Job
Responsible Third Party Official
Regulatory Technical Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K120863
Trade/Device Name: Wholey Guide Wire System
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II (Two)
Product Code: DQX
Dated: March 21, 2012
Received: March 22, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120863

Device Name: Wholey™ Guide Wire System

Indications for Use:

The Wholey Guide Wire System is intended to facilitate the placement and exchange of interventional devices during diagnostic or therapeutic interventional procedures. The guide wire can be torqued to facilitate navigation through tortuous arteries and/or avoid unwanted side branches.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120863